APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,946	03/24/2000	Frank R. Ruderman	MBHB00-203	1964

20306   7590   08/21/2002

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BLECK, CAROLYN M

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 08/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

	Application No.	Applicant(s)
Office Action Summary	09/534,946	RUDERMAN ET AL.
	Examiner	**Art Unit**
	Carolyn M Bleck	3626

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on _24 March 2000_ .

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) _1-20_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) _1-20_ is/are rejected.

7) ☒ Claim(s) _20_ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All b) ☐ Some * c) ☐ None of:

        1. ☐ Certified copies of the priority documents have been received.

        2. ☐ Certified copies of the priority documents have been received in Application No. _____ .

        3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

    a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application (PTO-152)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) ☐ Other: .

DETAILED ACTION

Notice to Applicant

1.   This communication is in response to the application filed 24 March 2000.

Claims 1-20 are pending. The IDS statement filed 24 March 2000 has been entered

and considered. Acknowledgement is made for a claim of domestic priority under 35

USC § 119(e) to provisional application 60/126,003 filed 24 March 1999 and provisional

application 60/168,354 filed 1 December 1999.

Specification

Applicant is reminded of the proper language and format for an abstract of the
disclosure.

The abstract should be in narrative form and generally limited to a single
paragraph on a separate sheet within the range of 50 to 150 words. It is important that
the abstract not exceed 150 words in length since the space provided for the abstract
on the computer tape used by the printer is limited. The form and legal phraseology
often used in patent claims, such as "means" and "said," should be avoided. The
abstract should describe the disclosure sufficiently to assist readers in deciding whether
there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information
given in the title. It should avoid using phrases which can be implied, such as, "The
disclosure concerns," "The disclosure defined by this invention," "The disclosure
describes," etc.

2.   The abstract of the disclosure is objected to because the abstract recites "The

invention" in line 1. It is requested this legal phraseology be corrected. See MPEP

§ 608.01(b).

3.   The use of the trademarks has been noted in this application. Some examples

are Microsoft® and NT 4.0 Option Pack ™ (pg. 6 lines 1-2), Microsoft ® WebTV ™ (pg.

15 lines 18-19), and OpenTV ® (pg. 16 line 11). They should be capitalized wherever

they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the

proprietary nature of the marks should be respected and every effort made to prevent

their use in any manner which might adversely affect their validity as trademarks. It is

requested the Applicant use proper notation for trademarks.

Claim Objections

4.   Claim 20 is objected under 37 CFR 1.75 as being a substantial duplicate of claim

19. When two claims in an application are duplicates or else are so close in content

that they both cover the same thing, despite a slight difference in wording, it is proper

after allowing one claim to object to the other as being a substantial duplicate of the

allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

5.   The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly
> claiming the subject matter which the applicant regards as his invention.

6.   Claims 5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention.

As per claim 5, line 1, "of claim" lacks proper antecedent basis as dependent

claim 5 does not refer to an independent claim. For purposes of applying prior art, claim

5 is assumed to be dependent on independent claim 1.

As per claim 9, line 2, "the records" lacks proper antecedent basis. For purposes

of applying prior art, "the records" of claim 9 is being interpreted as a means for storing

compliance data in databases.

Claim Rejections - 35 USC § 103

7.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

8.   Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over by

Levin et al. (5,724,580) in view of Surwit et al. (6,024,699).

(A) As per claim 1, Levin discloses a system for managing coronary disease data

(reads on "managing cardiovascular healthcare information") (col. 1 lines 9-18, col. 2

lines 39-45 and 50-57, and col. 11 lines 12-15) comprising:

(a) a centralized data management center for maintaining a record of data

received by and transmitted from relational databases relating to coronary disease data

(Abstract lines 11-14, Fig. 1-2, col. 10 lines 56-57, and col. 11 lines 5-10);

(b) a monitor displaying a menu (reads on "data entry interface") for entering all known and required information, including patient information such as name, birth date, sex, height, and weight, and test results, such ECG information, and storing the information and test results at the centralized data management center databases (Abstract lines 11-14, Fig. 1-2, col. 4 line 53 to col. 5 line 36, col. 10 lines 50-57, and col. 11 lines 5-10);

(c) processing means at the centralized data management center for analyzing patient test results using a coronary wellness master algorithm and artificial intelligence, such as ECG information, lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient (reads on "diagnostic engine") (col. 7 lines 55-63, col. 8 line 21 to col. 39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10);

(d) a monitor displaying a menu (reads on "physician data access interface") for providing a physician, such as a cardiologist, with the ability to access, display, review, and transfer information stored at the centralized data management center (col. 2 lines 1-15, col. 5 lines 49-67, and col. 11 lines 1-10).

Levin fails to expressly disclose a communication system allowing the physician to communicate cardiovascular healthcare management information to a patient. However, Levin includes communicating coronary illness information to and from a physician, such as a cardiologist, via communication network (Fig. 1-3 and 25A-25B, col. 2 line 62 to col. 3 line 10, col. 4 lines 31-55, col. 7 lines 33-47, and col. 7 line 64 to col. 8 line 7).

Surwit discloses a system for monitoring, diagnosing, prioritizing, and treating

chronic medical conditions of a plurality of remotely located patients, wherein treatment

information is provided to a patient via a computer network (Fig. 1 and 3, col. 2 lines 38-

55, col. 3 lines 24-38, col. 6 line 27 to col. 7 line 13, col. 9 lines 24-58, col. 18 line 45 to

col. 19 line 40).

At the time the invention was made, it would have been obvious to a person of

ordinary skill in the art to combine the aforementioned component of Surwit within the

system of Levin with the motivation of quickly and easily monitoring patients and

automatically identifying a patient with a medical condition, quickly preparing and

revising medicine dosages for a patient and then efficiently communicating revised

dosage information to a patient (Surwit; col. 2 lines 25-35), and reducing the costs of

medical treatment by providing a fast, effective technique for providing comprehensive

management of coronary patients based on risk factors including up to date diagnoses

and treatment information (Levin; col. 2 lines 16-49).

(B) As per claim 2, Levin discloses a storage means that stores information related to

coronary illness risk factors which have been established based on empirical data,

wherein the information allows physicians to determine the effectiveness of diagnoses

and treatments as the information is gathered over time and as the pool of treated

patients increases (Abstract lines 11-14, col. 6 line 3-15, and col. 10 lines 3-15). It is

respectfully submitted that the storage means disclosed by Levin is a form of a

knowledge base as the data collected in the database is a collection of knowledge of

specialists such as cardiologists, and the data collected will be used to effectively
identify patients at significant risk of sudden death and to quantify the success of
various treatments both for the patient pool and fro particular patients (col. 6 line 3-15).

(C) As per claims 3-5 and 11-12, Levin discloses processing means at the centralized
data management center for analyzing patient test results using a coronary wellness
master algorithm and artificial intelligence, such as ECG information, lipid data,
including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of
a patient (reads on "diagnostic engine") (Fig. 3, col. 5 lines 25-36, col. 6 lines 16-28, col.
7 lines 55-63, col. 7 line 64 to col. 8 line 7, col. 8 line 21 to col. 39, col. 10 lines 3-15,
col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10) wherein:

(a) the algorithms correlate test results with possible treatment recommendations
with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy,
antithrombotic therapy, diabetes, smoking cessation, body weight, and exercise (Fig.
25A-B and col. 10 lines 3-15);

(b) the algorithms correlate test results with possible or recommended
diagnoses, such as such as whether the levels of total cholesterol, LDL cholesterol, and
HDL cholesterol are acceptable or not, and the diagnosis classification for blood
pressure of a patient, wherein the classification includes normal, high-normal, mild
hypertension, moderate hypertension, severe hypertension, and very severe
hypertension (col. 8 line 21 to col. 9 line 39, col. 10 lines 3-15, and col. 11 line 10-15);

(c) the algorithms correlate diagnosis information with possible or recommended treatments (Fig. 25A-B, col. 5 lines 16-37, col. 6 line 16 to col. 7 line 47, col. 8 line 21 to col. 9 line 39, and col. 10 lines 3-15).

(D) As per claims 6-7, Levin discloses processing means at the centralized data management center for analyzing patient test results using a coronary wellness master algorithm and artificial intelligence, such as ECG information, lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient (reads on "diagnostic engine") (Fig. 3, col. 5 lines 25-36, col. 6 lines 16-28, col. 7 lines 55-63, col. 7 line 64 to col. 8 line 7, col. 8 line 21 to col. 39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10) wherein the processing means runs a lipid classification algorithm by inputting patient's LDL and HDL cholesterol values and checking the patient values against the upper limit for normal LDL and HDL cholesterol values, wherein the normal values are stored in the databases at the centralized data management center (Fig. 4 and 11, col. 5 lines 25-37, col. 8 line 21 to col. 9 line 40).

(E) As per claim 8, Surwit discloses allowing a case manager, including a physician, to select parameters from patient test results to view and compare over a period of time (Fig. 8-9, col. 17 line 40 to col. 18 line 30). The motivation for combining Surwit into Levin is given above in claim 1, and incorporated herein.

(F) As per claim 9, Surwit discloses transmitting physiologic or biologic data (e.g. body temperature and urine ketones), behavioral data (e.g. assessments related to diet, exercise, stress, the presence of illness) and patient medication intake data (all data reads on "compliance information") from a patient (col. 2 line 25 to col. 3 line 55 and col. 7 lines 40-63), wherein the data is stored in a database for review by a case worker such as a physician (col. 7 lines 40-63, col. 10 line 24 to col. 11 line 32, col. 13 lines 40-62, and col. 18 line 45 to col. 19 line 12). The motivation for combining Surwit into Levin is given above in claim 1, and incorporated herein.

(G) As per claim 10, Surwit discloses accessing chronic disease treatment information by a patient via a computer network through a menu driven display (reads on "patient access interface") (Fig. 1 and 3, col. 2 lines 38-55, col. 3 lines 24-38, col. 6 line 27 to col. 7 line 13, col. 7 line 40 to col. 9 line 22, col. 9 lines 24-58, col. 18 line 45 to col. 19 line 40). The motivation for combining Surwit into Levin is given above in claim 1, and incorporated herein.

(H) As per claim 13, Levin discloses a method for managing of coronary disease data (reads on "managing cardiovascular healthcare information") (col. 1 lines 9-18, col. 2 lines 39-45 and 50-57, and col. 11 lines 12-15) comprising:

(a) storing test result data, such as ECG signals of a patient, in a database (Fig. 3, 11-18, and 21-25A, Abstract lines 11-14, col. 1 lines 50-67, col. 2 lines 50-57, col. 3

lines 1-10, col. 5 lines 25-48, col. 7 lines 1-7, col. 11 lines 1-15 and col. 11 line 65 to col.

12 line 14, and col. 14 lines 5-8);

(b) providing test result data, such as ECG signals of a patient, to a physician,

including a cardiologist or primary care physician (col. 2 line 62 to col. 3 line 10, col. 4

lines 32-63, col. 5 lines 1-25 and line 49 to col. 6 line 15, col. 7 lines 1-47, col. 8 lines

21-60, col. 8 line 66 to col. 9 line 39, and col. 11 line 23-46);

(c) transferring diagnostic data, including coronary status, and specific

diagnoses, such as ischemia or thrombosis (Fig. 3, 11-16A, and 21-25B, col. 2 lines 50-

57, col. 3 lines 1-10, col. 7 lines 1-32, col. 8 lines 8-20, col. 11 line 65 to col. 12 line 14,

and col. 14 lines 5-8); and

(d) communicating treatment recommendations from a physician, such as a

cardiologist, via communication network (Fig. 1-3 and 25A-25B, col. 2 line 62 to col. 3

line 10, col. 4 lines 31-55, col. 7 lines 33-47, and col. 7 line 64 to col. 8 line 7).

Levin fails to expressly disclose providing treatment plan information to a patient

via a network. However, Levin includes communicating treatment recommendations to

and from a physician, such as a cardiologist, via communication network (Fig. 1-3 and

25A-25B, col. 2 line 62 to col. 3 line 10, col. 4 lines 31-55, col. 7 lines 33-47, and col. 7

line 64 to col. 8 line 7).

Surwit discloses a method for monitoring, diagnosing, prioritizing, and treating

medical conditions of a plurality of remotely located patients, wherein treatment

information is provided to a patient via a computer network (Fig. 1 and 3, col. 2 lines 38-

55, col. 3 lines 24-38, col. 6 line 27 to col. 7 line 13, col. 9 lines 24-58, col. 18 line 45 to col. 19 line 40).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned component of Surwit within the method of Levin with the motivation of quickly and easily monitoring patients and automatically identifying a patient with a medical condition, quickly preparing and revising medicine dosages for a patient and then efficiently communicating revise dosage information to a patient (Surwit; col. 2 lines 25-35), and reducing the costs of medical treatment by providing a fast, effective technique for providing comprehensive management of coronary patients based on risk factors including up to date diagnoses and treatment information (Levin; col. 2 lines 16-49).

(I) As per claim 14-16, Surwit discloses providing test result data, receiving diagnostic information from a physician, and receiving and providing information using internet protocols such as TCP/IP (Fig. 1 and 3, col. 2 lines 38-67, col. 3 lines 1-38, col. 6 line 27 to col. 7 line 13, col. 9 lines 24-58, col. 18 line 45 to col. 19 line 40). The motivation for combining Surwit into Levin is given above in claim 13, and incorporated herein.

(J) As per claim 17, Levin discloses analyzing test result data, such as ECG signals, lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient, and providing diagnosis information to a physician, such as whether the levels of total cholesterol, LDL cholesterol, and HDL cholesterol are

acceptable or not, and the diagnosis classification for blood pressure of a patient, wherein the classification includes normal, high-normal, mild hypertension, moderate hypertension, severe hypertension, and very severe hypertension (col. 8 line 21 to col. 9 line 39, col. 10 lines 3-15, and col. 11 line 10-15).

(K) As per claim 18, Levin discloses analyzing the diagnosis information and providing treatment recommendations with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy, antithrombotic therapy, diabetes, smoking cessation, body weight, and exercise, wherein a comprehensive written report is generated which include the treatment recommendations (Fig. 25A-B and col. 10 lines 3-15).

(L) As per claims 19-20, Surwit discloses transmitting physiologic or biologic data (e.g. body temperature and urine ketones), behavioral data (e.g. assessments related to diet, exercise, stress, the presence of illness) and patient medication intake data (all data reads on "compliance information") from a patient (col. 2 line 25 to col. 3 line 55 and col. 7 lines 40-63). The motivation for combining Surwit into Levin is given above in claim 13, and incorporated herein.

Conclusion

9.   The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. The cited but not applied prior art teaches a health care management system for use by hospitals, physicians, insurance companies, and health

maintenance organizations for inputting a health condition and identifying guideline

treatment options (5,583,758), a system and method for monitoring a group of patients

having a chronic disease or ongoing health condition (5,832,448 and 6,246,992), a

system and method for remotely monitoring a patient and for training the patient to

comply with a treatment plan for a health condition (5,960,403), a system and method

for providing computerized, knowledge-based medical diagnostic and treatment advice

(6,206,829), and a system and method for automated knowledge-based, long-term

patient disease management (6,234,964).

10.   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-

3981. The examiner can normally be reached on Monday-Friday, 8:30am – 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the Receptionist whose telephone number is (703)

306-1113.

11.   **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

        (703) 305-7687   [Official communications; including After Final
                                    communications labeled "Box AF"]

        (703) 746-8374   [Informal/ Draft communications, labeled
                                    ["PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

CB
August 14, 2002

JOSEPH THOMAS
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